Comment Form

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Document Title: Docket No. FDA-2021-N-0507 Medical Devices: Quality System Regulations Amendments

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#	Section	Comment/Proposed Change	Rationale
1	1A	"... FDA intends to converge its requirements with QMS requirements by other regulatory authorities." : What is the implication to access to records that FDA has not had access to in the past (e.g.; Management Review and Audit Reports) . Also, how will scheduling of audit agendas be handled.	ISO13485 Audits performed by other jurisdictions are done by 3rd party and these records are used as a part of setting the stage for the audits but not used to identify specific nonconformities. ISO audits are scheduled with formal agenda and times. FDA audits are not. What will the plan be going forward?.
2	1D	Cost estimates mention only the initial training of FDA personnel. What is FDA plan for ongoing training and link to training in other areas to support combination products, to support radiation specific regulations?	Training is generally handled as a standard part of the center but with the significance and

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			breadth of this change, Philips assumes that there will need to be an ongoing effort based on personnel's role.
3	VI	General Comment - transition strategy needs to include timeline to address all activities including updating of guidance documents to reflect changes of references from 820 to ISO 13485. Propose at least 2 years allowed from the time that the FDA issues this rule and all associated guidance have been updated.	Companies that don't have 13485 certifications will need more time. And the activities will be easier if all associated FDA guidance documents have appropriate linkages.
4	1E	Specific reference to ISO13485:2016. What will be FDA's plan as standard is updated?	2016 is already 6 years old and norm in standards is every 5 years update. Need to know how these will be handled by the FDA to ensure continued alignment. What will FDA do when ISO imposes the High Level Structure

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			(HLS) on a future 13485?
5	V Table 1	Concerned that table doesn't break down deep enough and address the linkages to other regulations and/or standards.	Concerned that some of the topics e.g.; complaint handling, vigilance/post market, supplier management, nonconforming materials may be listed too high a level. Unclear on how they would intend to audit (QSIT vs. MDSAP). Also, are these clear enough for the non-experienced?
6	VA	The scope of establishments covered by ISO13485 aren't just finished medical devices it should be as defined as who must register. Also what is the link to 807? Who Must Register, List and Pay the Fee | FDA	Clarity on scope and linkages. Details are needed
7	VB	Definitions – it's critical to know whether the FDA will have local adoption of definitions, remove conflict or adopt ISO13485. Good to see some specifics but not clear on whether complete but concerned with inconsistencies that have plagued industry for years. (e.g.; manufacture)	Clarity needed on scope of differences and how/where they will be reflected.
8	VD	• Appreciate the reference to the other applicable regulatory requirements, just hope that these references won't change the content of the way of working in the standard itself.	Potential clarity anticipated, but also want to

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		• Scope of device classification etc. should not change, that should stay the same and therefore, all medical devices as classified by FDA are within scope. Wording in document seemed somewhat confusing. Medical Device Classification Product Codes - Guidance for Industry and Food and Drug Administration Staff | FDA	ensure doesn't change interpretation of the standard. Note other regulators don't do that they just have their other regulations or standards identified elsewhere. Classification differences across jurisdictions so scope of standard is "medical devices".
9	VF1	Agree with record requirements, just unsure where they FDA intends to document these requirements – Guidance? All of these are norm with regards to an ISO audit performed today. Traceability, Reviewers, Approvers, Timely, etc.	Please clarity on how/where FDA plans to document requirements
10	VI	Timing seems appropriate for those manufacturers that already have compliance to ISO13485 in place however, I am concerned that it may be a challenge for small domestic only establishments.	I don't know the volume of sites impacted, however based on feedback from EU companies this could be a struggle to shift if they have

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			never had ISO13485.
11	IX	Respondents – it might be worthwhile to understand implications on each of the scope of present registrants as well as re-manufacturers. Since the FDA is also stating that servicing is included why doesn't this apply to all people doing servicing of finished medical devices?	Propose FDA specifically address remanufacturing and 3rd party servicers
12.	General	No specific comments on the costs, but it's never clear how these are calculated.	Further transparency on cost estimates would be appreciated.
13	§ 820.10 Requirements for a quality management system.	See excerpt below. (d) *Devices that support or sustain life.* Manufacturers of devices that support or sustain life, the failure of which to perform when properly used in accordance with instructions for use provided in the labeling can be reasonably expected to result in a significant injury, must comply with the requirements in Traceability for Implantable Devices, Clause 7.5.9.2 in ISO 13485, in addition to all other requirements in this part, as appropriate. This traceability requirement may be impossible to address with many components that are used in ventilators, and yet the risks associated are very different from those of implantable devices. Referring then to these requirements in ISO 13485 clause 7.5.9.2, it's listed there:	The FDA QS announcement presents a significant issue that Could impact ventilators and perhaps other products. In particular, those which incorporate OTS technology such as embedded PCs. This FDA document would extend the scope of ISO 13485 clause 7.5.9.2, traceability, to

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		7.5.9.2 Particular requirements for implantable medical devices The records required for traceability shall include records of components, materials, and conditions for the work environment used, if these could cause the medical device not to satisfy its specified safety and performance requirements. The organization shall require that suppliers of distribution services or distributors maintain records of the distribution of medical devices to allow traceability and that these records are available for inspection. Records of the name and address of the shipping package consignee shall be maintained (see 4.2.5).	include devices that sustain or support life, in addition to the existing scope of implantable devices. We do not believe it is the intent of FDA to extend the 7.5.9.2 to all medical devices. We propose this is deleted.
14	Part 820 subpart B - § 820.35 Control of records	*(b) Records of servicing activities.* In adhering to Clause 7.5.4 in ISO 13485, Servicing Activities, the manufacturer must record the following information, at a minimum, for servicing activities: … 6 Any test and inspection data Propose: Test and inspection be performed as required/defined by the legal manufacturer.	The requirement of Test and inspection data is ambiguous. If interpretation is that it applies to all service activities, this would result in Remote Servicing to be impacted since test or inspection may not be able to be done remotely. We would expect that Test and inspection data must be recorded

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			when defined by manufacturer. i.e. we would not retest a complete MR system when replacing a keyboard.
15	General	FDA has a new draft guidance on Computer Software Assurance that is on the A-list for publication in 2022. This guidance provides industry significant insight on the FDA's expectation for risk categorization of non product software and acceptable testing strategies. The alignment between ISO 13485 and 21 CFR 820 should take this guidance into consideration.	FDA has recognized that medical device industry has not moved forward on automation of quality system processes due to the perceived burden of validation. Propose the alignment between ISO 13485 and 21 CFR 820 should take the draft guidance on Computer software assurance is taken into consideration. This new guidance provides a huge step forward for industry to align

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			with the agency on expectations. ISO 13485 has also not been specific in their expectations and generally looked to the FDA's lead in this area.